

In re Application of: Niva SHAPIRA et al
Serial No.: 10/543,022
Filed: September 14, 2006
Office Action Mailing Date: November 16, 2010

Examiner: Audrea BUCKLEY
Group Art Unit: 1617
Attorney Docket: 32467
Confirmation No.: 4059

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1 and 63-66, 68-70, 74, 75 and 77-87 are in this Application. Claims 82-87 have been withdrawn from consideration for being directed to non-elected inventions. Claims 69 and 70 have been withdrawn from consideration for being directed to non-elected species.

Claims 1, 63-66, 68, 74, 75 and 77-81 have been rejected under 35 U.S.C. § 103.

Claims 2-62, 67, 71-73 and 76 have been canceled in a previous response. Claims 1, 68-70, 74, 77 and 78 have been amended herewith.

Amendments To The Claims

35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner has stated that claims 1, 63-66, 68, 74, 75 and 77-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 1, 68-70, 74, 77 and 78 have been amended.

Specifically, the Examiner has stated that claim 1 recites the limitation “the antioxidant” and that it is unclear what the relationship is between “the antioxidant” and “the antioxidant component”.

Claim 1 has been amended so as to recite “antioxidant” instead of “antioxidant component” and “the at least one antioxidant” instead of “the antioxidant”. Similarly, claim 1 has been further amended so as to recite “antacid” instead of “antacid component”.

Applicant submits that the relationship between the limitation “the at least one antioxidant” and the antecedent “at least one antioxidant” is now clear.

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Amended claim 1 is supported, for example, by claim 35 of the instant application as originally filed, which describes a relationship between an antioxidant weight and an antacid weight, rather than a relationship between a weight of a component which comprises an antioxidant and a weight of a component which comprises an antacid.

In accordance with the claim language of amended claim 1, claims 68-70 have been amended so as to recite “at least one antacid” instead of “antacid component”; claim 74 has been amended so as to recite “at least one antioxidant” instead of “antioxidant component”; and claims 77 and 78 have been amended so as to recite “the at least one antioxidant” instead of “the antioxidant”.

Applicant submits that the above amendments are cosmetic and do not affect the scope of the claims.

Applicant therefore believes to have overcome the Examiner’s rejections.

35 U.S.C. § 103 Rejection
(Lambert et al. in view of Grimberg)

The Examiner has stated that claims 1, 63-66, 68, 75 and 77-81 are rejected under U.S.C. § 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al., and further in view of Grimberg. The Examiner’s rejection is respectfully traversed. Claims 1, 68-70, 74, 77 and 78 have been amended.

Specifically, the Examiner has stated that Lambert et al. teach an antacid formulation comprising an antacid, an antioxidant (ethoxyquin), and a carrier, and that the carrier comprises steam rolled oats, which inherently comprise plant-derived antioxidants as evidenced by Handelman et al., and which comprise 14.1 % of the total antacid formulation, and 37.8 % of the total antacid and antioxidant component weight. The Examiner has further stated that Grimberg teaches an increase of one pH unit.

In addition, the Examiner has stated that the rolled oats in the teaching of Lambert constitute the antioxidant component required by the claim.

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As discussed hereinabove, claim 1 has been amended so as to clarify that the recited weight ratio refers to an antioxidant (and antacid) and not a component (e.g., rolled oats) which merely comprises a small amount of antioxidant (or antacid).

Lambert et al. teach a use of 0.02-1.0 % antioxidant, preferably ethoxyquin, in an antacid formulation comprising 11.0-45.0 % antacid, whereby the antioxidant is added in order to prevent breakdown of certain components of the formulation prior to consumption of the formulation (see, for example, column 2, lines 48-54, and column 3, lines 9-13, of Lambert et al.).

Handelman et al. teach that oat fractions comprise an antioxidant capacity equivalent to about 2-8 $\mu\text{mol/g}$ of Trolox, and that most of the antioxidants in the oat fractions are phenolics such as caffeic acid (molecular weight = 180) and ferulic acid (molecular weight = 194). See, for example, the Materials and Methods section; page 4890, Table 2; and the paragraph bridging pages 4891 and 4892, in Handelman et al. Thus, the teachings of Handelman et al. indicate that antioxidants comprise a very small fraction (e.g., less than 0.1 %) of the weight of oats. Furthermore, Handelman et al. teach that steam treatment reduces the antioxidant capacity of oats (see, for example, final paragraph of page 4890, therein).

However, a formulation comprising 14.1 % rolled oats, wherein less than 0.1 % of the weight of the rolled oats consists of antioxidant, will comprise a very low concentration of antioxidants (i.e., less than about 0.014 %) derived from the rolled oats. Hence, the antioxidants in the rolled oats are relatively negligible in comparison to the 0.02-1.0 % antioxidant which Lambert et al. teach as an additive. Such a result is expected, as if the rolled oats comprised a significant concentration of antioxidant, there would be no apparent reason for Lambert et al. to teach addition of 0.02-1.0 % antioxidant.

As the formulation taught by Lambert et al. comprises only negligibly more than 0.02-1.0 % antioxidant, wherein the antioxidant is merely for preventing breakdown of certain components of the antacid formulation, Lambert et al. neither

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teach nor suggest use of a relatively large proportion of antioxidant, as recited in claim 1.

For example, as stated by the examiner, Lambert et al. teach a formulation comprising, by mass, 0.1 % antioxidant (ethoxyquin) and 23.45 % antacid. Thus, Lambert et al. teach the use of an amount of antioxidant which is less than 0.5 % of the total weight of antioxidant and antacid in the formulation.

As Lambert et al. teach an antioxidant merely for preventing breakdown of certain components of the antacid formulation, one of ordinary skill in the art would have no motivation for using a larger quantity of antioxidant. Indeed, one of ordinary skill in the art would be motivated to use as little antioxidant as is feasible in a formulation taught by Lambert et al., as the antioxidant is an additive which is not intended as an active ingredient of the formulation taught therein.

Furthermore, Grimberg et al. does not even remotely suggest a use of a relatively large proportion of antioxidant.

In sharp contrast, claim 1 relates to a composition for potentiating antioxidative activities, which comprises substantial proportions of both antacid and antioxidant, such that the amount of the antioxidant in the composition is at least 10 %, but no more than 95 %, of the total weight of antacid and antioxidant.

Applicant therefore submits that claim 1, as well as claims 63-66, 68, 75 and 77-81 which depend therefrom, are not obvious over Lambert et al. in view of Grimberg, and are therefore allowable.

35 U.S.C. § 103 Rejection

(Lambert et al. in view of Grimberg and Howard et al.)

The Examiner has stated that claim 75 is rejected under U.S.C. § 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al., as applied to claims 1, 63-66, 68, 74 and 77-81, and further in view of Howard et al. The Examiner's rejection is respectfully traversed.

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Specifically, the Examiner has stated that Howard et al. teach a flavonol-containing composition wherein at least 25 % of the composition includes polyphenols, and at least 1 % is flavonol. The Examiner has further stated that it would have been obvious to include the polyphenol and flavonol antioxidants disclosed by Howard et al. into the formulation of Lambert et al., which also teach the benefits of the antioxidant component, that all of the formulations are to be taken orally as a health benefit.

As discussed hereinabove, Lambert et al. teach a formulation with a small proportion (0.02-1.0 %) of antioxidant (preferably ethoxyquin), as well as rolled oats, which comprise a negligibly small additional amount of antioxidant.

As further discussed hereinabove, Grimberg et al. does not even remotely suggest a use of a larger proportion of antioxidant.

Thus, Lambert et al., either alone or in combination with Grimberg, fails to teach or suggest including an amount of antioxidant in the composition which is at least 10 % of the total weight of antacid and antioxidant.

Furthermore, it is not clear to Applicant what the Examiner refers to when stating that Lambert et al. “teaches the benefits of the antioxidant component”.

If the “antioxidant component” refers to the ethoxyquin antioxidant taught by Lambert et al., then modifying the formulation of Lambert et al. by replacing the ethoxyquin with a polyphenol-containing composition taught by Howard et al. will merely result in a small proportion of polyphenol antioxidant, which is less than 10 % of the total weight of antacid and antioxidant.

If, however, the “antioxidant component” refers to the rolled oats taught by Lambert et al. (on the grounds that rolled oats are a component which comprises an antioxidant), then one of ordinary skill in the art would not interpret Lambert et al. as teaching “the benefits of the antioxidant component”, as Lambert et al. neither describes the rolled oats as such, nor teaches or suggests that the benefits of rolled oats are in any way related to the fact that they comprise minute quantities of antioxidants.

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Rather, Lambert et al. explicitly teaches that the rolled oats are part of a carrier (see, for example, column 3, lines 41-42, therein) of a formulation adapted for administration to horses (see, for example, column 1, lines 8-10, therein).

It would be apparent to one of skill in the art that the purpose of the rolled oats is to serve as a food for horses, and not to provide antioxidants, because:

a) it is well known that oats are given to horses as food (see, for example, the definition of “Oats” in *A Dictionary of the English Language* [Johnson, Samuel (1755) London: J. & P. Knapton] “A grain, which in England is generally given to horses, but in Scotland supports the people”); and

b) the amount of antioxidants in the rolled oats is insignificant, as discussed hereinabove.

In contrast, Howard et al. teaches a composition comprising wine-derived material including at least 25 % polyphenols (see, for example, Abstract, thereof).

It would not be obvious to replace the rolled oats component in the formulation taught by Lambert et al. with the wine-derived material taught by Howard et al., because wine-derived material having a high concentration of polyphenols is not recognized as a suitable food for horses. It would not be obvious to replace the rolled oats component taught by Lambert et al. with any substance which does not serve the purpose intended for the rolled oats component, as taught by Lambert et al.

Moreover, contrary to the Examiner’s statements, one of skill in the art would not be motivated to combine the composition taught by Howard et al. with the formulation taught by Lambert et al. merely because both are to be taken orally as a health benefit.

As discussed hereinabove, Lambert et al. teach an antacid formulation adapted for horses. Howard et al. teach a composition designed to prevent coronary heart disease (CHD) and stroke in humans (see, for example, column 9, lines 6-26, in Howard et al.). There is no apparent rationale to combine a formulation for treating one disorder in one species with a composition for preventing an unrelated disease in

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an entirely different species, even if both can be described broadly as providing a “health benefit”.

The Examiner has not even made clear what such a combination would allegedly be useful for. If the suggested combination is for preventing coronary heart disease (CHD) and stroke in humans, the cited art does not even remotely suggest a rationale for including an antacid. If the suggested combination is for serving as an antacid for horses, wherein the antioxidant is intended merely to preserve the formulation prior to use (as taught by Lambert et al.), the cited art does not even remotely suggest a rationale for including a higher proportion of antioxidant than is taught by Lambert et al.

In view of the above, one of ordinary skill in the art would not combine the teachings of Lambert et al., Grimberg, and Howard et al. in any way which would even remotely suggest including an amount of antioxidant (let alone a polyphenol antioxidant recited in claim 75) in the composition which is at least 10 % of the total weight of antacid and antioxidant.

Applicant therefore submits that claim 75 is not obvious over Lambert et al. in view of Grimberg and Howard et al., and is therefore allowable.

Examination of Generic and Non-Elected Claims

In view of the amendments made to the claims and the arguments recited herein it is believed that the claims are allowable with respect to the elected species and hence examination of all claims in this Application in their generic context and with respect to all the species recited therein is respectfully requested.

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In view of the above amendments and remarks it is respectfully submitted that claims 1, 63-66, 68-70, 74, 75 and 77-81 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Enclosures:

- Petition for Extension (1 Month)